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November 24, 1998

Honorable Commissioner of Patents
and Trademarks
Washington, D.C. 20231

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Re: **U.S. Patent Application Serial No. 08/993,564**
For: **CHIMERIC EMBRYOS AND ANIMALS**
CONTAINING HUMAN CELLS
Filed: **December 18, 1997**
Our Reference No. **45010-00601**

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**MINIMUM CUSTOMER
SERVICE CENTER**

Dear Sir:

Submitted herewith is a Supplemental Petition Under 37 C.F.R. 1.182 with Exhibits A and B together with a law firm check in the amount of \$130.00. The Commissioner is hereby authorized to charge any additional fees due, or credit any overpayment to Deposit Account 03-2469.

Also enclosed please find a postcard indicating the documents being filed. Please date-stamp the card indicating receipt of the attached papers and return it to us.

Respectfully Submitted,

PATRICK J. COYNE, Reg. No. 31,821

JOHN N. COULBY, Reg. No. P43,565

Enclosures



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re
Application of: **STUART A. NEWMAN**

Serial No.: **08/993,564**

Filed: **December 18, 1997**

For: **CHIMERIC EMBRYOS AND ANIMALS CONTAINING HUMAN CELLS**

Atty. Docket #: **45010-00601**

Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

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MATRIX CUSTOMER
SERVICE CENTER

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Supplemental Petition Under 37 C.F.R. 1.182

Applicant Dr. Stuart Newman, and co-owners Dr. Stuart Newman and The Foundation on Economic Trends, respectfully submit this Supplemental Petition to the Commissioner, requesting clarification of the Office's current interpretation, regulatory guidance, and policies with respect to the patentability of chimeric or hybrid organisms comprising human cells or portions thereof. The Commissioner appears to have taken inconsistent positions on the patentability of inventions containing human and non-human components. Applicant is writing requesting clarification of the Office's policies on the patentability of these inventions.

Applicant has applied for a patent for an invention entitled Chimeric Embryos and Animals Containing Human Cells, Serial No. 08/993,564. In discussions of the application with third parties,

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the application has received some media attention, including a segment on ABC World News Tonight and articles in the journal Nature and the Washington Post. In response to this publicity, the Commissioner issued a document entitled "Media Advisory" on April 2, 1998. A copy of the Commissioner's Media Advisory is attached as Exhibit A.

On November 12, 1998, an application by Advanced Cell Technology Co. of Worcester, Massachusetts, was discussed in an article appearing on the front page of *The New York Times*. The article discussed an experiment conducted more than two years ago in which scientists now employed by Advanced Cell Technology placed the nucleus isolated from a human cell into a denucleated bovine egg. A copy of this article is attached as Exhibit B. The human/bovine hybrid progressed through several cell divisions, according to the inventor, Jose Cibelli. Advanced Cell Technology indicates that it has applied for a patent on this human/bovine hybrid. Although the invention is not the same as that claimed by Applicant, the resulting organism claimed in the Cibelli patent application is a human/bovine hybrid organism.

The Media Advisory reacting to Applicant's invention noted a number of potential grounds for denial of Applicant's application. The application had not yet been examined, raising concern by Applicant of bias or prejudgment of the merits of the patentability of Applicant's invention by the Office. Commissioner Lehman has been quoted as saying that he will deny patents on "monsters" and other "immoral" inventions (*The Washington Post*, May 11, 1998). In addition, the Commissioner has made reference in public speaking engagements that the Office will not allow patents on "monsters", in apparent reference to Applicant's application.

Applicant acknowledges that, prior to the passage of the current Patent Act in 1952, judicial authority vested with the Patent Office discretion to reject applications on moral grounds.

Nonetheless, the 1952 Act, under which the Patent Office currently operates, contains no provision or authority for the Commissioner to reject an application on moral grounds. Applicant is unaware of any situation in which the Commissioner has ever rejected an application on moral grounds under the 1952 Act.

The Commissioner's April 1998 Media Advisory states "It is the position of the PTO that inventions directed to [a] human/non-human chimera could, under certain circumstances, not be patentable because, among other things, they would fail to meet the public policy and morality aspects of the utility requirement". Applicant is concerned regarding the use of any such "moral grounds" as a criteria for patentability under the utility requirement. The stated utility of Applicant's invention -- for use as a medical research model, in areas including, but not limited to, drug testing, organ transplantation and related studies, toxicity studies and cell biology and cell development research -- is at least as beneficial as that reported for the Cibelli invention.

Regardless of how the merits of the utility disclosed in Applicant's application are viewed, its utility is certainly no less than that of numerous patents that have been issued for transgenic animals containing human material. Patent applications, including Cibelli's, are currently pending or have been granted for a range of transgenic animals containing human genes, chromosomes, cells, tissues, and organs. Is it now the position of the Office that any animal containing human biological material might "fail to meet the public policy and morality aspects of the utility requirement?" Does the Office have some formal or informal regulatory guidance as to what kind and how much human genetic or other human biological material transferred to another animal -- for which a patent is being sought -- is unacceptable on "moral" grounds?

Applicant is concerned regarding the inconsistent and disparate treatment accorded by the Office to these two public announcements. Following public announcement of Applicant's application, the Commissioner's Media Advisory was released the same day. That Advisory implicated the patentability of Applicant's invention. Following the public announcement of Cibelli's human/bovine application by Advanced Cell Technology, in contrast, no such statement has been issued by the Commissioner. To Applicant's knowledge, the Commissioner has made no public statement in any form as to the nature or patentability of the Cibelli invention.

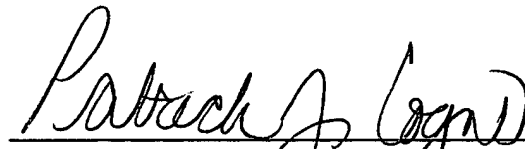
Applicant is concerned regarding the Commissioner's reaction of issuing a Media Advisory following the announcement of Applicant's invention, and the inconsistent reaction to the Cibelli announcement. Applicant believes that the issuance of a Media Advisory, as well as any external statements, or potentially internal statements by the Commissioner within the Office, commenting on Applicant's case, could bias the review of Applicant's invention and have a chilling effect on the fair and objective consideration of the patentability of the invention. As a result of the Commissioner's Media Advisory and public statements, Applicant is reasonably concerned that the patentability of the subject matter of its invention has been prejudiced, not only in the eyes of the public but in the eyes of the Patent & Trademark Office examining corps.

Applicant responded to the Commissioner's Media Advisory by filing a Supplemental Petition on April 24, 1998. That Petition, as well as the original Petition, was denied, without substantive response. Applicant respectfully requests clarification from the Commissioner as to why similar public comments have not been made regarding the Cibelli invention. If the Commissioner has reformulated his views regarding the patentability of the subject matter of the above-referenced applications, Applicant respectfully requests that the Commissioner issue a clarification, in order

to reduce the chance that Applicant's application is unduly prejudiced. If, on the other hand, the Commissioner's view remains as stated in the Media Advisory, Applicant respectfully requests an explanation of why the public announcement of the Cibelli invention has not elicited similar comments from the Commissioner, or the Patent & Trademark Office, and why the Cibelli application warrants differential treatment.

Respectfully submitted,

Dated: November 24, 1998

A handwritten signature in cursive script, appearing to read "Patrick J. Coyne", written over a horizontal line.

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